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<b>TRANSMITTAL FORM</b>  <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/782,871	
	Filing Date	February 23, 2004	
	First Named Inventor	Malcolm King	
	Art Unit	1617	
	Examiner Name		
Total Number of Pages in This Submission		Attorney Docket Number	11157-74

ENCLOSURES (check all that apply)		
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Bereskin & Parr		
Signature			
Printed Name	Micheline Gravelle		
Date	February 2, 2005	Reg. No.	40,261

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# Bereskin & Parr

INTELLECTUAL PROPERTY LAW

February 2, 2005

Micheline Gravelle B.Sc., M.Sc. (Immunology)  
416 957 1682 mgravelle@bereskinparr.com

Your Reference: 10/782,871  
Our Reference: 11157-74

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
U.S.A

Dear Sirs:

**Re: Filing of an Information Disclosure Statement**  
**United States Patent Application No. 10/782,871**  
**Filed On: February 23, 2004**  
**Entitled: USE OF CHARGED DEXTRAN AS A MUCOACTIVE AGENT AND**  
**METHODS AND PHARMACEUTICAL COMPOSITIONS RELATING**  
**THERE TO**  
**Inventor: Malcolm King**

In accordance with 37 CFR 1.97 and 1.98, and in recognition of the duty of disclosure set forth in 37 CFR 1.56, Applicant hereby submits an Information Disclosure Statement on Form PTO/SB/08a containing a listing of patents and other publications of which Applicant is aware. Applicant is also submitting the references listed on the Information Disclosure Statement.

All of the patents and publications submitted herewith are in the English language. Accordingly, a concise explanation of the relevance of the documents is not required.

The Examiner is requested to indicate consideration of these documents by initialling the appropriate column.

Applicants reserve the right to contest the applicability of any of these documents as prior art against the subject application. If the Examiner has any questions concerning this Information Disclosure Statement, he/she is requested to contact the undersigned. Entry of the enclosed Information Disclosure Statement is believed to be in order and is respectfully requested.

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TORONTO MISSISSAUGA WATERLOO

This Information Disclosure Statement is being filed before the issuance of a first official action, and therefore no fees are required. However, please charge our deposit account No. 02-2095 if such a fee is required.

Respectfully submitted,

**MALCOLM KING**

A handwritten signature in cursive script, appearing to read "M. Gravelle", written over a horizontal line.

Micheline Gravelle  
Registration No. 40,261

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*(Use as many sheets as necessary)*

Sheet	1	of	6
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<b>Application Number</b>	10/782,871
<b>Filing Date</b>	February 23, 2004
<b>First Named Inventor</b>	Malcolm King
<b>Art Unit</b>	1617
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	11157-74

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	1	WO 91/15216 PCT	10-17-1991	Kennedy		
	2	WO 95/17898	07-06-1995	Novadex Pharm Ltd.		
	3	WO 93/08810 PCT	05-13-1993	Carrington Lab INC		
	4	EP 0177783	04-16-1986	Kanto Ishi Pharma et al		

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2

of 6

**Complete if Known**

Application Number	10/782,871
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**NON PATENT LITERATURE DOCUMENTS**

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	1	KING, M., AND B.K. RUBIN. 1996. Mucus physiology and pathophysiology: Therapeutic aspects. Chapter 13 of: Derenne, J.P., W.A. Whitelaw, and T. Similowski, eds. Acute Respiratory Failure in COPD (Lung Biology in Health and Disease Series) Marcel Dekker, New York, 391-411.	
	2	RUBIN, B.K., R.P. TOMKIEWICZ, AND M. KING. 1997. Mucoactive agents: Old and new. Chapter 7 of: Wilmott, R.W., ed. The Pediatric Lung. Birkhauser, Basel, 155-179.	
	3	SHEFFNER, A.L. 1963. The reduction in vitro in viscosity of mucoprotein solutions by a new mucolytic agent, N-acetylcysteine. Ann. N. Y. Acad. Sci. 106:298-310.	
	4	DASGUPTA, B., AND M. KING. 1996. Reduction in viscoelasticity of cystic fibrosis sputum in vitro with combined treatment by Nacystelyn and rhDNase. Pediatr. Pulmonol. 22:161-166.	
	5	APP, E.M., R. KIESELMANN, D. REINHARDT, H. LINDEMANN, B. DASGUPTA, M. KING, AND P. BRAND. 1998. Sputum rheology changes in cystic fibrosis lung disease following two different types of physiotherapy: Flutter vs. autogenic drainage. Chest 114:171-177.	
	6	FENG, W., H. GARRETT, D.P. SPEERT, AND M. KING. 1998. Improved clearability of cystic fibrosis sputum with dextran treatment in vitro. Am. J. Respir. Crit. Care Med. 157:710-714.	
	7	WILLS, P.J., R.L. HALL, W.M. CHAN, AND P.J. COLE. 1997. Sodium chloride increases the ciliary transportability of cystic fibrosis and bronchiectasis sputum on the mucus-depleted bovine trachea. J. Clin. Invest. 99:9-13.	
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	11	DAVASKAS, E., S.D. ANDERSON, J.D. BRANNAN, H.K. CHAN, S. EBERL, AND G. BAUTOVICH. 1997. Inhalation of dry-powder mannitol increases mucociliary clearance. Eur. Respir. J. 10:2449-2454.	

Examiner Signature		Date Considered	
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			Application Number	10/782,871	
			Filing Date	February 23, 2004	
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			Examiner Name		
			Attorney Docket Number	11157-74	
Sheet	3	of	6		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	12	SHIBUYA, Y., P.J. WILLS, S. KITAMURA, AND P.J. COLE. 1997. The effect of lactose on mucociliary transportability and rheology of cystic fibrosis and bronchiectasis sputum. Eur. Respir. J. 10:321s.	
	13	FUCHS, H.J., D.S. BOROWITZ, D.H. CHRISTIANSEN, E.M. MORRIS, M.L. NASH, B.W. RAMSEY, B.J. ROSENSTEIN, A.L. SMITH, AND M.E. WOHL. 1994. Effect of aerosolized recombinant human DNase on exacerbations of respiratory symptoms and on pulmonary function in cystic fibrosis. N. Engl. J. Med. 33:637-648.	
	14	RANASINHA, C., B. ASSOULI, S. SHAK, D. CHRISTIANSEN, H. FUCHS, D. EMPEY, D. GEDDES, AND M. HODSON. 1993. Efficacy and safety of short-term administration of aerosolized recombinant human DNase I in adults with stable stage cystic fibrosis. Lancet 342: 199-202.	
	15	KING, M., AND B.K. RUBIN. 1999. Mucus controlling agents: Past and present. In: Rau, J.L., ed. Aerosolized Drugs for the Respiratory Tract. Respir Care Clinics N Amer. in press.	
	16	FENG, W., S. NAKAMURA, E. SUDO, M.M. LEE, A. SHAO, AND M. KING. 1999. Effects of dextran on tracheal mucociliary velocity in dogs in vivo. Pulm. Pharmacol. Ther. 12:35-41.	
	17	LEE, M.M., AND M. KING. 1998. Effect of low molecular weight heparin on the elasticity of dog mucus. Clin. Invest Med. 21:S 102.	
	18	LEE M.M, H. GARRETT, E. SUDO, W.A. BOYD, AND M. KING. 1998. Mucociliary clearance increase due to low molecular weight heparin. Pediatr. Pulmonol. 386:S 17.	
	19	APP, E.M., J.G. ZAYAS, AND M. KING. 1993. Rheology of mucus and transepithelial potential difference: Small airways vs. trachea. Eur. Respir. J. 6: 67-75.	
	20	KING, M., S. KELLY, AND M. COSIO. 1985. Alteration of airway reactivity by mucus. Respiration Physiol. 62:47-59.	
	21	KING, M. 1988. Magnetic microrheometer. In: Braga, P.C., and L. Allegra, eds. Methods in Bronchial Mucology. Raven Press, New York, 73-83.	
	22	KING, M. 1987. The role of mucus viscoelasticity in cough clearance. Biorheology 24: 589-597.	

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Sheet	4	of	6	Attorney Docket Number	11157-74

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	23	RUBIN, B.K., O. RAMIREZ, J.G. ZAYAS, B. FINEGAN, AND M. KING. 1990. Collection and analysis of respiratory mucus from individuals without lung disease. Am. Rev. Respir. Dis. 141:1040-1043.	
	24	DAVASKAS, E., S.D. ANDERSON, I. GONDA, S. EBERL, S. MEIKLE, J.P. SEALE, AND G. BAUTOVICH. 1996. Inhalation of hypertonic saline aerosol enhances mucociliary clearance in asthmatic and healthy subjects. Eur. Respir. J. 9:725-732.	
	25	ROBINSON, M., A. HEMMING, J.A. REGNIS, D.L. BAILEY, M. KING, W. FENG, G.J. BAUTOVICH, AND P.T.P. BYE. 1998. Improved mucociliary clearance following nebulisation with hypertonic saline in adults with cystic fibrosis. In: Baum, G., ed. Cilia, Mucus and Mucociliary Interactions. Marcel Dekker, New York, 265-280.	
	26	TOMKIEWICZ, R.P., W.A. BOYD, W. FENG, E.M. APP, B.K. RUBIN, AND M. KING. 1997. Tracheal clearance and mucus rheology in healthy dogs after aerosolization of 3% and 7% hypertonic saline. Am. J. Respir. Crit. Care Med. 155:A780.	
	27	NAKAMURA S, SUDO E, W. FENG, M.M. LEE, W.A. BOYD, AND M. KING. 1998. Effects of hypertonic saline aerosolization on tracheal mucus clearance and mucus rheology in healthy dogs. Eur. Respir. J. 12(S28): 180s.	
	28	WINTERS, S.L., AND D.B. YEATES. 1997. Role of hydration, sodium, and chloride in regulation of canine mucociliary transport system. J. Appl. Physiol. 83:1360-1369.	
	29	TOMKIEWICZ, R.P., E.M. APP, G.T. DE SANCTIS, M. COFFINER, P. MAES, B.K. RUBIN, AND M. KING. 1995. A comparison of a new mucolytic N-acetylcysteine L-lysinate with N-acetylcysteine: Airway epithelial function and mucus changes in dog. Pulm. Pharmacol. 8:259-265.	
	30	SUDO, E., M.M. LEE, W.A. BOYD, AND M. KING. 1998. Effect of methacholine and uridine-5' triphosphate on tracheal mucus rheology in mice. Pediatr. Pulmonol. S 17:229.	
	31	TAI, S., H. KAI, T. KIDO, Y. ISOHAMA, K. TAKAHAMA, AND T. MIYATA. 1997. Effect of human neutrophil elastase on tracheal mucociliary transport in anesthetized quails. Jpn. J. Pharmacol. 75:439-442.	
	32	KING, M., A. GHAHARY, R. FRANKLIN, M. HIRJI, D. MALCHENKO, W.A. BOYD, H. GARRETT, AND M.M. LEE. 1999. Studies on aerosolized low mol. wt. heparin as a mucokinetic agent in dogs. Am. J. Respir. Crit. Care Med. 159:A474.	
	33	BJORCK, S., E. JENNISCHE, A. DAHLSTROM, AND H. AHLMAN. 1997. Influence of topical rectal application of drugs on dextran sulfate-induced colitis in rats. Dig. Dis. Sci. 42:824-832.	

Examiner Signature		Date Considered	
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	34	LORENTSEN, K.J., C.W. HENDRIX, J.M. COLLINS, D.M. KORNHAUSER, B.G. PETTY, R.W. KLECKER, C. FLEXNER, R.H. ECKEL, AND P.S. LIETMAN. 1989. Dextran sulfate is poorly absorbed after oral administration. Ann. Int. Med. 111: 561-566.	
	35	BELLER, F.K., ZIMMERMAN, R.E., AND H. NIENHAUS. 1986 Biochemical identification of the mucus of pseudomyxoma peritonei as the basis for mucolytic treatment. Am. J. Obstet. Gynecol. 155:970-3.	
	36	RAO N. V. et al.; "Sulfated Polysaccharides Prevent Human Leukocyte Elastase-Induced Acute Lung Injury and Emphysema in Hamsters", American Review of Respiratory Disease, vol. 142, no. 2, 1990, pp. 407-412.	
	37	MOTOJIMA S. et al: "Effects of Anionic Polyelectrolyte Substance on Damages to Respiratory Epithelium Induced by Eosinophil Peroxidase", Dokkyo Journal of Medical Sciences, MIBU, JP, vol. 21, no. 2, 1994, pp. 123-134	
	38	FATH M. A. et al.: "Interaction of Secretory Leukocyte Protease Inhibitor with Heparin Inhibits Protease Involved in Asthma", Journal of Biological Chemistry, American Society of Biological Chemists, Baltimore, MD, US, vol. 273, no. 22, May 29, 1998, pp. 13563-13569.	
	39	COYLE A. J. et al: "Role of Cationic Proteins in the Airway Hyperresponsiveness due to Airway Inflammation", American Journal of Respiratory and Critical Care Medicine, American Lung Association, New York, NY, US, vol. 150, no. 5, part 2, Nov. 1994, pp. S63-71.	
	40	BARGHOUTH SAMEER et al.: "Inhibition by Dextran of Pseudomonas Aeruginosa Adherence to Epithelial Cells", American Journal of Respiratory and Critical Care Medicine, vol. 154, no. 6, part. 1, 1996, pp. 1788-1793.	
	41	COYLE ANTHONY J. et al.: "Cationic Proteins Induce Airway Hyperresponsiveness Dependent on Charge Interactions", American Review of Respiratory Disease, vol. 147, no. 4, 1993, pp. 896-900.	
	42	BARROWCLIFFE, MICHAEL P. et al.: "Pulmonary Clearance of Radiotracers After Positive End-Expiratory Pressure or Acute Lung Injury", J. Appl. Physiol. (1989), 66(1), 288-94.	
	43	BARROWCLIFFE M. P. et al.: "Clearance of Charged and Uncharged Dextran from Normal and Injured Lungs", Journal of Applied Physiology, vol. 68, no. 1, 1990. pp. 341-347.	
	44	ATHAMNA ABED et al. "Adherence of Mycoplasma Pneumoniae to Human Alveolar Macrophages", Fems Immunology and Medical Microbiology, vol. 15, no. 2-3, 1996, pp. 135-141.	

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/782,871		
		Filing Date	February 23, 2004		
		First Named Inventor	Malcolm King		
		Art Unit	1617		
		Examiner Name			
Sheet	6	of	6	Attorney Docket Number	11157-74

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	45	PAUL M. QUINTON, Physiological basis of cystic fibrosis: a historical perspective. Physiol Rev. 1999 Jan;79(1 Suppl):S3-S22.	

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